REMARKS

1. General Matters

1.1. The withdrawal of claim 11 is acknowledged.

1.2. The typographical error at P1, L5 of the specification has been corrected.

With regard to "per os", this is Latin for "by mouth", and has been standard medical terminology for centuries.

1.3. In claim 1, "matrix;" is now "matrix,".

1.4. Claim 2 has been cancelled, so the objection to improper markush form is moot.

1.5. Claim 3 has been amended so dosage form is singular.

1.6. The abbreviation HPMC in claim 4 has been spelled out.

1.7. The antecedent basis and Markush group form problems in claim 5 have been corrected.

1.8. The requested "and" has been inserted into claim 7.

1.9. This resolves all objections to the claims and specification.

1.10. Additionally, we have amended claim 1 to recite "for oral administration" and made corrections to claims 7, 8 and 10. The "such as" clause in claim 8 has been transferred to new claim 12.

2. Definiteness Issues (OA pp. 5-6)

Claims 5, 6 and 8 were rejected as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The terms "respiratory stimulants" and "stomachic digestants", recited in claim 5, were both objected to on the basis that the terms fall within the categories "drugs for

respiratory organs" and "digestive drugs", respectively. In addition, the term "drugs for blood or body fluid" was objected to on the basis that this limitation can read on an array of pharmaceutically active agents. All three terms have now been deleted from claim 5. The term "at the upper parts of the gastric-intestine", recited in claim 6, has been replaced by "in the stomach"; support for this can be found on page 11, lines 10-11 of the description in the published PCT application. The term "coatings" in claim 8 was objected to because the term can be used in a manner applied for both active and non-active components. The expression "non-active" has been added prior to "coatings" in claim 8. The word "other" in claim 8 was objected to on the basis that it is unclear as to what additional additives Applicant is making reference to. The word "other" has been deleted from claim 8.

3. Prior Art Issues (OA pp. 6-14)

3.1. Regarding the observations made by the examiner in respect to the novelty of claims 1-5 and 8-10 in view of Skinner (US 6210710), please note that the limitations of original claims 2 and 9 have been incorporated into claim 1. Claim 1 now recites a controlled-release dosage form, suitable for oral administration, comprising gellan gum and one or more hydrophilic polymers selected from guar gum, hydroxypropyl methylcellulose, carboxymethyl cellulose sodium salt and xanthan gum, and further comprising at least one drug.

Skinner discloses a composition comprising at least first and second components and a medicament, where the first component is selected from derivatives of hydroxypropylcellulose (HPC), ethylcellulose (EC) and hydroxyethylcellulose (HEC) and the second component is at least one other polymer. Gellan gum is included in a list of

suitable polymers. However, Skinner fails to disclose the compositions of the present invention, comprising gellan gum and one or more hydrophilic polymers selected from guar gum, hydroxypropyl methylcellulose, carboxymethyl cellulose sodium salt and xanthan gum. Moreover, Skinner does not provide any working example in which the composition includes gellan gum. Thus, it cannot be held that Skinner discloses the present invention.

3.2. Claims 1, 6 and 7 were rejected as being obvious over Skinner (US6210710). However, in light of the claim amendment, and for the same reasons specified above with respect to the alleged anticipation by Skinner, we believe this rejection is now moot.

3.3. Regarding the observations made by the examiner in respect to the novelty of the claims in view of Illum (US 5935604), please note that the dosage form of the present invention has been limited to forms suitable for oral administration. We construe this language as requiring that the form be capable (when administered in suitable amount) of achieving a therapeutic effect. Illum provides a nasal drug delivery composition comprising nicotine and an ion-exchange material which forms a complex with the nicotine, such as a polymer material or a bioadhesive microsphere. Illum does not relate to an orally administered dosage form for a gastric environment. Therefore, US 5935604 cannot deprive the present invention, as defined in the amended claims, of novelty. We note that Illum's claims recite "for nasal administration".

3.4. Claims 1-10 were rejected as being unpatentable over Baichwal (US 5958456) in view of Skinner (US 6210710). Applicants respectfully traverse this rejection.

Baichwal describes a controlled release pharmaceutical formulation comprising a medicament and a sustained release

excipient comprising a gelling agent, a hydrophobic material and an inert diluent. The invention relates to the discovery that by granulating the sustained release excipient with a solution or dispersion of a hydrophobic material prior to admixture of the excipient with the medicament, the medicament may provide therapeutically effective blood levels for extended periods to time. The dissolution profiles of the formulations of Baichwal are given in Examples 1-12, all of which include a hydrophobic polymer within the formulation (e.g., carboxymethylcellulose, cellulose acetate phthalate, polyvinyl acetate phthalate, hydroxypropylmethylcellulose phthalate, ethylcellulose). Moreover, Baichwal is completely silent concerning gellan gum.

The present invention relates to a dosage form comprising a medicament and a matrix of hydrophilic polymers and more specifically, a matrix of gellan gum and at least one of guar gum, hydroxypropyl methylcellulose, carboxymethyl cellulose sodium salt and xanthan gum. The invention is based on the discovery that these specific combinations have the ability to form a stable, fast swellable gel in vivo when introduced to the gastric environment, and are thus prevented from exiting the stomach into the intestine. Baichwal does not teach or suggest these combinations.

The combination of the teachings of Baichwal and Skinner would not lead the skilled artisan to the present invention. Even if the gellan gum taught by Skinner was used in the formulation of Baichwal, the formulation would include a hydrophobic polymer in accordance with the teachings of Baichwal, and the hydrophilic matrices of the present

invention would not be obtained.

Respectfully submitted,

BROWDY AND NEIMARK, P.L.L.C.
Attorneys for Applicant(s)

By: _____
Iver P. Cooper
Registration No. 28,005

IPC:lms
Telephone No.: (202) 628-5197
Facsimile No.: (202) 737-3528
G:\BN\P\Pyer\Hoikhman1\Pto\2010-09-29 ptoamendment.doc